Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 30-71 are pending in the application, with claims 30, 40, 55, 66, 68, 69 and 70 being the independent claims. Claims 30-36, 40, 41, 46, 49, 55, 56 and 66-71 are amended. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

In-person interview of May 28, 2003

Applicants' representative thanks the Examiner and the Examiner's supervisor for the courtesies extended during the in-person interview of May 28, 2003. During the interview, Applicants' representative discussed with the Examiner the differences between the claimed invention and Patterson *et al.*, U.S. Patent No. 5,941,869. Specifically, Applicants' representative explained that the present invention is directed to a kit for transvenously accessing the heart, and for penetrating the wall of the right atrium so as to gain entry into the pericardial space. Patterson *et al.*, on the other hand, is directed to angioplasty and atherectomy-type procedures, not for transvenously accessing the heart, much less entering the pericardial space.

Rejections under 35 U.S.C. § 102(e)

Claims 30-36, 45-47, 49, 50, 55, 56, 61-63 and 66-71 stand rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by Patterson *et al.* During the interview, the Examiner indicated that she considered the claims to be directed to the use in any heart, including animal hearts, rather than specifically directed to use in the human heart.

In response, all of the independent claims have been amended to recite that the present invention is directed for use in the human heart.

The Examiner indicated that she considered the language in the claims regarding transvenous access to the pericardial space as being in the nature of "intended use," to which the Examiner did not accord patentable weight. In response, all of the independent claims have also been amended to use functional language, rather than the alleged intended-use language. Specifically, claim 30 has been amended to recite:

> a leading guide wire **for entering** the human heart transvenously . . . the leading guide wire being . . . and having a diameter sufficiently small **for passing** through a lumen of said infusion guide wire . . . [and] **for passing** through and protruding from a distal end of said infusion guide wire . . . a distal end **for penetrating** a wall of the right atrium.

Claim 30 has also been amended to recite that the infusion guide wire and the leading guide wire together have sufficient flexibility "for simultaneously passing transvenously through the guide catheter into the right atrium." Applicants respectfully submit that this language addresses the Examiner's concerns regarding the earlier language being merely intended use language, rather than features to be accorded patentable weight. The functional language of claim 30 is in contrast with the disclosure of Patterson *et al.* The catheter of Patterson *et al.* is not designed for transvenous use. In fact, there are numerous references in Patterson *et al.* of use in arteries, rather than in veins, which tend to be much more delicate than arteries. A surgeon would not normally use a catheter that is designed for arterial use in transvenous applications.

Furthermore, as discussed during the interview, the catheter of Patterson *et al.* is not designed for entry into the heart. In fact, nowhere in Patterson *et al.* is there a mention of entering the right atrium of the heart.

The catheter of Patterson *et al.* is also not designed for penetrating the wall of the right atrium so as to access the pericardial space. In fact, attempting to do so with the catheter of Patterson *et al.* would be extremely dangerous to the patient. If a large hole were made in the wall of the right atrium, such as would be made with the catheter of Patterson *et al.*, there is a high probability that the patient would die, absent immediate open-heart surgery. Thus, by amending the language of the claims to recite functional features, Applicants respectfully submit that independent claim 30 is distinguishable over Patterson *et al.*, which is the primary reference used for the rejections in the Office Action. Accordingly, Applicants respectfully request that the rejection of claim 30 be reconsidered and withdrawn.

Independent claim 40 has been amended to recite "a guide catheter for transvenous insertion into a right atrium of said human heart." As discussed above, this functional language distinguishes over Patterson *et al.* Similarly, claim 40 has been amended to recite:

> an infusion guide wire . . . **for transvenous insertion** into said right atrium and having sufficient stiffness **for transvenously traversing** a patient's anatomy . . . a hollow leading wire **for passing** through a lumen of said infusion guide wire . . . wherein said leading guide wire has sufficient length **for passing through and protruding from** a distal end of said infusion guide wire.

Applicants believe that this functional language distinguishes over Patterson *et al.*, as discussed above. Accordingly, Applicants respectfully request that the rejection of claim 40 be reconsidered and withdrawn.

Independent claims 55, 66 and 68-70 have been similarly amended to recite functional language, rather than the alleged intended use language. Although their scope is not identical to that of either claim 30 or claim 40, claims 55, 66 and 68-70 are distinguishable over Patterson *et al.* at least for the same reasons as those set forth above

for claims 30 and 40. Accordingly, Applicants respectfully request that the rejections of these claims under 35 U.S.C. § 102(e) be reconsidered and withdrawn.

A number of dependent claims have also been amended, to the extent possible, to recite functional aspects, rather than intended-use. These claims are allowable at least because their base claims are allowable, as well as due to the features recited therein.

A number of claims have also been amended to correct minor informalities, and to correct antecedent basis.

Rejections under 35 U.S.C. § 103(a)

A number of dependent claims stand rejected as being allegedly unpatentable over Patterson *et al.*, or over Patterson *et al.* in view of Helmus *et al*, U.S. Patent No. 5,569,197, or as being allegedly unpatentable over Patterson *et al.* in view of Motolla *et al.*, U.S. Patent No. 5,957,901. As noted above, these dependent claims are allowable at least because their base claims are allowable, as well as due to the features recited therein. Accordingly, Applicants respectfully request that their rejections be reconsidered and withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

Please amend claims 30-36, 40, 41, 46, 49, 55, 56 and 66-71 as follows:

30. (Twice Amended) A kit for transvenously accessing the pericardial space between a human heart and its pericardium to perform a medical procedure on the human heart, the kit comprising:

a guide catheter;

an infusion guide wire coaxial with said guide catheter substantially throughout a length of said guide catheter; and

a leading guide wire for entering the human heart transvenously in combination with the infusion guide wire, the leading guide wire being coaxial with said infusion guide wire and having a diameter sufficiently small [to be passed] for passing through a lumen of said infusion guide wire, said leading guide wire having a sufficient length [to pass] for passing through and [protrude] protruding from a distal end of said infusion guide wire, [and] the leading guide wire having a distal end [capable of] for penetrating a wall of [the] a right atrium of the [subject's] human heart,

wherein said infusion guide wire and said leading guide wire both have sufficient flexibility [to permit said infusion guide wire and said leading guide wire to be] for simultaneously [passed] passing transvenously through said guide catheter into the right atrium [of the subject's heart via a transvenous route].

31. (Amended) The kit of claim 30, wherein said infusion guide wire has a diameter sufficiently small [to be passed] for passing through a lumen of said guide catheter, said infusion guide wire having a sufficient length [to be passed] for passing through said guide catheter into [the] said right atrium [of the subject's heart] via a transvenous route.

32. (Amended) The kit of claim 30, [further comprising:

a] wherein said guide catheter [having] has sufficient length and flexibility [to be inserted] for transvenous insertion into [the] said right atrium [of a subject's heart via a transvenous route].

33. (Amended) The kit of claim 30, wherein said infusion guide wire has sufficient flexibility [to permit said infusion guide wire to conform] for conforming at

least partially to [the] a contour of [the] said human heart when said infusion guide wire is extended outward from a distal end of said guide catheter and into [the] said pericardial space.

34. (Twice Amended) The kit of claim 33, wherein said infusion guide wire functions as an aspiration catheter having a lumen of sufficient diameter [so that] for passing said infusion guide wire [may be passed] over said leading guide wire and into[the] said pericardial space for [the] removal of fluid from [the] said pericardial space [to treat] for treating cardiac tamponade.

35. (Amended) The kit of claim 30, wherein said leading guide wire has sufficient flexibility [to permit said leading guide wire to conform] for conforming at least partially to [the] a contour of [the] said human heart when said leading guide wire is extended outward from a distal end of said guide catheter and into [the] said pericardial space.

36. (Twice Amended) The kit of claim 35, wherein said infusion guide wire functions as an aspiration catheter having a lumen of sufficient diameter [so that] for passing said infusion guide wire [may be passed] transvenously over said leading guide wire and into [the] said pericardial space for [the] removal of fluid from [the] said pericardial space [to treat] for treating cardiac tamponade.

40. (Twice Amended) A kit for transvenously accessing [the] a pericardial space between a human heart and its pericardium to perform a medical procedure on [the] said human heart, the kit comprising:

a guide catheter for transvenous insertion into a right atrium of said human heart [having sufficient length and flexibility to be inserted into the right atrium of a subject's the heart via a transvenous route];

an infusion guide wire within said guide catheter for transvenous insertion into said right atrium and having sufficient stiffness [to] for transvenously traversing [traverse] a patient's anatomy [to be inserted into the right atrium of a subject's heart via a transvenous route];

a hollow leading guide wire for passing through a lumen of said infusion guide wire and for extending through said infusion guide wire [catheter and having a diameter sufficiently small to be passed through a lumen of said guide catheter],

wherein said leading guide wire has sufficient length [to pass] for passing through and [protrude] protruding from a distal end of said infusion guide wire [catheter], and has a distal end [capable of] for penetrating a wall of [the] said right atrium [of the subject's heart], [and sufficient flexibility to permit] said leading guide wire [to be passed] being sufficiently flexible for passing through said guide catheter and into [the] said right atrium [of the subject's heart] via a transvenous route.

41. (Amended) The kit of claim 40, wherein said leading guide wire has sufficient flexibility [to permit said leading guide wire to conform] for conforming at least partially to [the] a contour of [the] said human heart when said leading guide wire is extended outward from a distal end of said guide catheter and into [the] said pericardial space.

46. (Amended) The kit of claim 30, wherein said kit is adapted to perform a surgical procedure on [the] said human heart.

49. (Amended) The kit of claim 30, wherein said infusion guide wire and said leading guide wire jointly have sufficient pushability [to penetrate] for penetrating into [the] said pericardial space through [a] said wall of [a] said right atrium [of the heart] without kinking.

55. (Amended) A dual guide wire for transvenously accessing a pericardial space between a human heart and its pericardium to perform a medical procedure on [the] said human heart comprising:

an infusion guide wire; and

a leading guide wire for insertion through [the] said infusion guide wire and having a diameter sufficiently small [to be passed] for passing through a lumen of said infusion guide wire, said leading guide wire having a sufficient length [to pass] for passing through and [protrude] protruding from a distal end of said infusion guide wire, [and] said leading guide wire having a distal end [capable of] for penetrating a wall of [the] a right atrium of [the subject's] said human heart,

wherein said dual guide wire [has sufficient flexibility to pass] is sufficiently flexible for transvenously passing [through a guide catheter] into [the] said right atrium [of the subject's heart via a transvenous route], and wherein said dual guide wire is

sufficiently pushable for penetrating [sufficient pushability to penetrate] into [the] said pericardial space through a wall of [a] said right atrium [of the heart] without kinking.

56. (Amended) The dual guide wire of claim 55, wherein said dual guide wire has sufficient pushability [to penetrate] for penetrating into [the] said pericardial space through said wall of said right atrium [of the heart] without kinking while being aligned tangential to said wall [of said right atrium].

66. (Amended) A dual guide wire for transvenously accessing a pericardial space between a human heart and its pericardium [to perform] for performing a surgical procedure on [the] said human heart comprising:

an infusion guide wire; and

a leading guide wire [insertable] for transvenous insertion into a right atrium of [the] said human heart through said infusion guide wire and for performing a surgical procedure on said human heart, said leading guide wire [and] having a distal end [capable of] for penetrating a wall of [the] said right atrium [of the heart], wherein said infusion guide wire and said leading guide wire jointly have sufficient pushability [to penetrate the] for penetrating said wall of [the] said right atrium into [the] said pericardial space without kinking[,

wherein the dual guide wire may be used to perform a surgical procedure on the heart].

67. (Amended) The kit of claim 66, wherein said infusion guide wire and said leading guide wire jointly have sufficient pushability [to penetrate] for penetrating into [the] said pericardial space through [a] said wall of the right atrium [of the heart] without kinking while being aligned tangential to said wall.

68. (Amended) A dual guide wire for transvenously accessing a pericardial space between a human heart and its pericardium comprising:

an infusion guide wire for transvenous insertion into said human heart; and

a leading guide wire [insertable] for insertion into [the] said human heart through said infusion guide wire,

wherein said dual guide wire has sufficient pushability [to penetrate] for penetrating into [the] said pericardial space through a wall of a right atrium of [the] said human heart without kinking, and has sufficient steerability [to be steered] for steering to any location within [the] said pericardium.

69. (Amended) A dual guide wire for transvenously accessing a pericardial space between a human heart and its pericardium for aspiration of fluid from [the] said pericardial space to treat cardiac tamponade comprising:

an infusion guide wire for aspiration of fluid from [the] said pericardial space to treat cardiac tamponade; and

a leading guide wire [insertable] for insertion into [the] said human heart through said infusion guide wire and having a distal end [capable of] for penetrating a wall of a right atrium of [the] said human heart,

wherein said dual guide wire has sufficient pushability [to penetrate the] for penetrating said wall of [the] said right atrium into [the] said pericardial space without kinking.

70. (Amended) A dual guide wire for transvenously accessing a pericardial space between a human heart and its pericardium to implant a surgical device within [the] said human heart comprising:

an infusion guide wire for transvenous insertion into said human heart; and

a leading guide wire [insertable] for insertion into [the] said human heart through said infusion guide wire and having a distal end [capable of] for penetrating a wall of a right atrium of [the] said human heart, wherein said infusion guide wire and said leading guide wire jointly have sufficient pushability [to penetrate the] for penetrating said wall of [the] said right atrium into [the] said pericardial space without kinking,

wherein [the] said dual guide wire is adapted for implantation of a surgical device within the human heart.

71. (Amended) The dual guide wire of claim 70, wherein [the] said dual guide wire is adapted for implantation of [the] said surgical device within a coronary artery of [the] said human heart.